IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAMELA BUTLER, et al.,	)	
	)	
Plaintiffs,	)	Case No. 4:18-cv-01701-AGF
v.	)	
	)	Lead Case
MALLINCKRODT LLC, et al.,	)	
	)	**ORAL ARGUMENT REQUESTED**
Defendants.	)	

DEFENDANTS' JOINT MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY OF PLAINTIFFS' EXPERT JAMES CLARK, PH.D

Defendants Mallinckrodt LLC ("Mallinckrodt") and Cotter Corporation (N.S.L.) ("Cotter") jointly move the Court for an Order excluding the testimony of Plaintiffs' toxicologist James Clark, Ph.D., because he is not qualified to testify as an expert in radiation dosimetry and his opinions and bases do not satisfy the requirements of Federal Rule of Evidence 702 or *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

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I. INTRODUCTION

Plaintiffs hired Dr. Clark, who is not a radiation specialist, to quantify the radiation dose each Plaintiff allegedly received. Plaintiffs' dose reconstruction is a key component of proving their claims in this litigation. Yet Dr. Clark has no professional training in the field of radiation science or radiation dose reconstruction (or any related discipline). To the extent he has any experience, he developed it during and for this litigation. Prior to *McClurg*, Dr. Clark had never worked in this field. His lack of training and knowledge is readily apparent.

For this litigation exclusively, Dr. Clark invented his own radiation dose calculation that: (1) does not consider plaintiff-specific information in his possession; (2) cannot be reproduced, traced, or tested; and (3) contains an 83% error rate in its calculations. Dr. Clark then compared his unreliable doses to a fictional background amount of radiation he developed to give the impression that his doses are "above background." But Dr. Clark's fictional background level of radiation is unsupported by any literature or professional experience and is orders of magnitude lower than the universally accepted amount of natural background radiation. Dr. Clark's testimony should be struck in its *entirety* and is not reliable or probative for the following reasons, each of which independently supports exclusion:

- Dr. Clark's dose reconstruction methodology is improper according to the very source on which he claims to base his methodology.
- Dr. Clark based his doses for each Plaintiff on false assumptions and incorrect data applied uniformly across all four Plaintiffs.
- Dr. Clark invented the "natural background" he relies on as a basis for his risk calculations for this litigation, and it is universally contradicted by every authoritative source.
- Dr. Clark's "maximum" doses are contrived from flawed methodology rendering them not only unreliable but factually impossible according to Plaintiffs' own expert.
- Dr. Clark is simply not qualified to give the opinions he offers in this case.

Dr. Clark developed his dose reconstruction methodology and his imaginary background numbers for this litigation to elicit a specific litigation result. His work is contradicted by universally accepted science, as well as the literature on which it purports to rely. He even failed to apply his own methodology correctly in this case. The analytical failures in his analysis confirm what his lack of experience, training, and qualifications suggest: Dr. Clark is not qualified to provide any opinions in this case, and he must be excluded.

II. BACKGROUND

Plaintiffs allege that their four distinct illnesses were caused by exposure to radiation released in excess of federal regulations by Mallinckrodt and Cotter. (Doc. #1, ¶ 24.) A complete background regarding the sites and alleged exposures at issue may be found in Defendants' memoranda in support of their motions to exclude the testimony of Dr. Wells.

III. STANDARD OF REVIEW

Federal Rule of Evidence 702 governs the admissibility of expert testimony. Under Rule 702, a witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue:

(b) the testimony is based upon sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the witness has applied the principles and methods reliably to the facts of the case.

Rule 702 imposes a "gate-keeping function" on district courts to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert,* 509 U.S. at 589. "The objective of the *Daubert* inquiry 'is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs the same level of intellectual

rigor that characterizes the practice of an expert in the relevant field.'" *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 722 (8th Cir. 2015) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). Moreover, the party offering the expert testimony bears the burden of establishing its admissibility. *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006) (citing *Daubert*, 509 U.S. at 589–90).

Daubert, enumerates several non-exclusive factors to guide this Court's reliability analysis:

- whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability,
- whether the technique or theory has been subjected to peer review or publication,
- the known or potential rate of error of the technique or theory when applied,
- the existence and maintenance of standards and controls, and
- whether the technique or theory has been generally accepted in the scientific community.

Daubert, 509 U.S. at 593–94; Fed. R. Evid. 702, advisory committee's notes. "*Daubert's* progeny provides additional factors such as: whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Lauzon v. Senco Prods, Inc.*, 270 F.3d 681, 687 (8th Cir. 2001).

Further, "[w]hen the analytical gap between the data and proffered opinion is too great, the opinion must be excluded." *Marmo*, 457 F.3d at 758. And when an opinion rests on faulty or insufficient data, or otherwise ignores relevant data, the district court should exclude the testimony. *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000).

IV. ARGUMENTS & AUTHORITIES

A. Dr. Clark's Methodology Contradicts Its Own Source.

1. The Source for Dr. Clark's Method of Individual Dose Reconstruction States It Should Not Be Used for Individual Dose Reconstruction.

On June 18, 2018, the Agency for Toxic Substances and Disease Registration ("ATSDR") issued a draft community screening report for Coldwater Creek (the "Draft ATSDR Report", attached as **Exhibit A**) for public comment. The ATSDR released its final report 22 months later on April 30, 2019. (Clark *Butler* 41:4–7, attached as **Exhibit B**; Final ATSDR Report, attached as **Exhibit C**.) The ATSDR Report is a public health assessment for radiation exposure for individuals living in and around Coldwater Creek. It makes conservative assumptions, intentionally designed to overstate potential risk, about possible recreational and residential exposures to radiation from Coldwater Creek in order to assess the risk of these exposures from a public protection perspective.

Because of its public protection perspective, the ATSDR Report assumes exposure amounts above the exposures of any typical individual. Yet, despite making these higher assumptions, the ATSDR determined that the "radiological doses associated with Coldwater Creek exposures were lower than those known to cause specific cancers or other harmful effects." (Final ATSDR Report, p. 31.) Dr. Clark admitted that he based his entire dose reconstruction and the opinions on which it rests on the *Draft* ATSDR Report. (Clark *Butler* 41:1–25.)

The most significant problem with Dr. Clark's use of the ATSDR methodology is that he uses it in a manner the ATSDR expressly rejected. The ATSDR Report states repeatedly that its screening methodology based on averages and inflated assumptions should "not be used for a detailed dose reconstruction"—*i.e.*, precisely how Dr. Clark used it:

- The ATSDR methodology has an "inherent inability to predict individual exposure and risk" (p. F-15);

- "…our methods are intended to obtain a conservative estimate of potential exposures using exposure point concentrations and other assumptions. The estimated exposures do not necessarily apply to individuals or even an average individual" (p. F-37);

- "The report cannot say whether or not an individual's illness was caused by exposure to contaminants from Coldwater Creek" (p. F-21); and

- "We recognize that this approach [i.e., the method it uses to estimate lifetime risks] would not be used in a detailed dose reconstruction. We believe the improved accessibility of the calculations for the general public outweighs any inaccuracies introduced by our method" (p. F-40).

(Final ATSDR Report, April 2019, pp. F-11, F-40; *see also* Clark *Butler* 221:10–222:11.)

Dr. Clark admitted that the Draft ATSDR Report warned that its screening methodology should "not be used for a detailed dose reconstruction." (Clark *Butler* 138:12–22; Clark *Czapla* 33:5–34:11, see attached as **Exhibit D**.) Yet Dr. Clark consciously disregarded this admonition because he disagreed with it and wanted to use the ATSDR methodology to reconstruct individual doses for Plaintiffs. (Clark *Butler* 41:1–25; 138:12–139:22.) Dr. Clark claimed—without any authority—that he could do so because he "particularized" his analysis for each Plaintiff. (Clark *Butler* 139:2–22.) But Dr. Clark did not "particularize" anything. By his own admission, he adopted the Draft ATSDR Report's overly conservative screening assumptions designed for regulatory and public health purposes and ignored actual information from the Plaintiffs, as discussed in further detail below in Section B.1. Without any reliable or scientific basis, Dr. Clark simultaneously claimed his methodology was sound because it was in the ATSDR Report and, paradoxically, rejected ATSDR's warning not to use its methodology precisely as Dr. Clark employed it.

This Court cannot satisfy its evidentiary gatekeeping role under *Daubert* if it admits Dr. Clark's opinions, as they contradict his own source, are not the "product of reliable principles and methods," and have not been "reliably applied . . . to the facts of the case." Fed. R. Evid. 702; *see Daubert*, 509 U.S. at 593–94. In a similar context, the court in a Price-Anderson Act case excluded

a radiation dosimetry expert's testimony where he attempted to estimate dose from *internal alpha* radiation based on chromosome damage using a methodology for dose estimation of *external gamma* radiation—contrary to the scientific literature. *Good v. Flour Daniel Corp.*, 222 F. Supp. 2d 1236, 1245 (E.D. Wash. 2002). The court took particular issue with the expert's inability to justify his methodology's deviation from the scientific literature. *Id.*

Here, far worse than the studies in *Good*, the report Dr. Clark relied on for his methodology makes clear that it should not be used for individual dose reconstruction because of its inherent limitations and inaccuracies in that context. And like the expert in *Good*, Dr. Clark offers no scientific authority or support for how or why he can use the ATSDR's public health screening assessment in this way when the ATSDR said he should not. In short, Dr. Clark's methodology is not reliable, contradicts his own source, and should be excluded.

2. Dr. Clark's Methodology Is Litigation-Made, Not Science-Made, and Ignores Corrections and Changes the ATSDR Made.

Dr. Clark's methodology fails for yet another reason: as he admits, it (1) has been used only in this litigation for individual dose reconstruction, and (2) was invented just for this litigation. (Clark *Butler* 255:17–256:7; 131:21–24.) This is a hallmark of unreliable expert testimony that should not make its way to a jury. *See, e.g.*, *Kumho Tire Co.*, 526 U.S. at 157 (expert properly excluded when there was no evidence methodology was used by other experts in industry and no supporting literature).

Dr. Clark has a history of using unreliable methodologies that are made for litigation and not science. As this Court knows, in the lead *McClurg* litigation, Dr. Clark first tried to perform individual radiation dose assessments using the Department of Energy's Residual Radiation or "RESRAD" model. When that failed, Dr. Clark tried to switch to another Department of Energy modeling tool called "GENeration II" or "GENII." (Clark *McClurg* 10/4/17, 122:25–123:4,

attached as **Exhibit E**.) But again, Dr. Clark so egregiously misused the model that its creator, Bruce Napier, described Dr. Clark's work as follows:

> The output of the dose calculations was reported incorrectly, in a manner that makes the results meaningless. *In addition, the nature of the error indicates that Dr. Clark has no grasp of the basic radiation dosimetry principles used in U.S. and international radiation protection regulations.*

(Napier Affidavit,[1] p. 1, attached as **Exhibit F** (emphasis added).) Here, as noted above, Dr. Clark has tried to use yet another methodology—this time the ATSDR's—contrary to the author's instructions.

Compounding his error, Dr. Clark relied on the Draft ATSDR Report exclusively rather than the final report. (Clark *Butler* 41:1-25; 253:3–5.) And despite the draft nature of the report, Dr. Clark did not reliably apply the report's methodology or verify its applicability, but rather used it without any verification at all. (Clark *Butler* 97:5–11.) Indeed, by the time of his deposition, the Final ATSDR Report had been published for nearly five months. Yet, exemplifying his lack of scientifically rigorous analysis, Dr. Clark did not even know the differences between the draft and final report because he did not bother to look for any. (Clark *Butler* 125:9–17.)

There are in fact stark differences between the draft and final report, which Dr. Clark failed to consider and apply.

First, the estimated doses contained in the draft report decreased from the draft report to the final report, yet Dr. Clark's did not. (Draft ATSDR Report, June 18, 2018, p. 21; *cf.* Final ATSDR Report, April 30, 2019, p. 22.)

Second, the Draft ATSDR Report identified the potential for elevated cancer risks for cancers of the bone, lungs, red marrow, skin, and breast. (Draft ATSDR Report, p. 21.) Of these,

[1] Dr. Napier reviewed Dr. Clark's report and provided his affidavit on Dr. Clark's misuse of the GENII model. Dr. Napier was not compensated for his review or affidavit.

only breast cancer and bone cancer are relevant here: Ms. Butler was diagnosed with breast cancer, and Dr. Clark used a bone cancer coefficient in his effective dose for all four Plaintiffs. The Final ATSDR Report acknowledged and corrected critical errors in the draft report as to both the breast and bone calculations: (1) it changed its conclusion to state there was not any elevated breast cancer risk (Final ATSDR Report, p. 22); and (2) it corrected the bone cancer coefficient, which had previously been overstated by a *factor of ten* (Clark *Butler* 266:6–269:10). Dr. Clark did not know these changes occurred and did not correct his calculations. (Clark *Butler* 125:9–17.) As a result, even if one were to accept Dr. Clark's prohibited use of the ATSDR report in this manner, his risk calculations remain inflated and inconsistent with the Final ATSDR Report. (Clark *Butler* 266:6–269:10.)

In short, Dr. Clark's methodology is fundamentally unsound because it misused the Draft ATSDR Report for individual dose reconstruction despite the explicit instructions in the draft and final report not to do so. (Clark *Butler* 138:22–139:22.) Dr. Clark admitted no one else has used the ATSDR methodology or report in the same way. (Clark *Butler* 255:17—256:7; Clark *Czapla* 136:6–24). And Dr. Clark neither corrected his analysis to account for the errors in the Draft ATSDR Report that were fixed in the Final ATSDR Report, nor could he have done so because he did not bother to look at the differences. (Clark *Butler* 125:9–17.) The result is an unsound methodology, unreliably applied, and it is not fit for a jury.

B. Dr. Clark's Testimony Contradicts the Facts and Data, and the Gap Between His Estimated Doses and the Record Evidence Is Fatal.

1. Dr. Clark's Doses Defy Plaintiffs' Actual Exposure Information.

As a threshold matter, Dr. Clark's methodology fails *Daubert* because it ignored readily available information about each Plaintiff's actual exposure that contradicts the premises of Dr. Clark's analyses.

First, Dr. Clark did not use the information in Plaintiffs' Court-ordered questionnaires that set forth their exposure histories. (Clark *Butler* 191:24–195:5.) He acknowledged he had access to Plaintiffs themselves whenever he wanted, could have asked them additional questions if he wanted to, and ultimately did interview them—but did not incorporate this information into his opinions. (Clark *Butler* 212:4–10.) In other words, Plaintiffs' actual history near Coldwater Creek did not matter to Dr. Clark's opinion:

> Q: So regardless of what they said in your interview or the plaintiff's questionnaire about how much they would have played along the creek, you were just going to assume it was – if they were an adult, it would have been 2 hours a day, 96 days a year, no matter what; correct?
>
> A: Correct. That's an average value.

(Clark *Butler* 192:13–19.) Quite obviously, one cannot perform an individual dose calculation if one does not consider the individual's exposure history.

Second, Dr. Clark ignored the Plaintiffs' deposition testimony. The **only** adjustment Dr. Clark made to the hypothetical baseline assumptions he derived from the Draft ATSDR Report was to adjust the number of years Plaintiffs lived in the area, but he did this based on estimates and not the Plaintiffs' actual testimony:

> Q: Earlier you told me that you particularized your dose reconstruction, and so you didn't agree with ATSDR's suggestion that their methodology should not be used in a dose reconstruction like this; is that correct?
>
> A: Right. And I told you that I did that by adjusting the time period when they were exposed.
>
> Q: But you did not particularize it for each of the plaintiffs in their actual deposition testimony and what they testified to; correct?
>
> A: Correct. Because they didn't testify to that until after I wrote the reports. Months later they testified.

(Clark *Butler* 183:5–18.)

Dr. Clark's excuse that he did not have Plaintiffs' deposition testimony at the time of his report rings hollow: he could have elicited this information when interviewing Plaintiffs. And even after Plaintiffs' depositions, Dr. Clark still refused to update his reports or rely on the transcripts because he stated, without substantiation, "depositions are scary things" and "[t]here's a little recall bias on their part." (Clark *Butler* 54:1–55:6; *see also* Clark *Czapla* 11:5–7.) Moreover, for the one effort Dr. Clark actually made to "particularize" the ATSDR's assumptions—adjusting years in exposure area—he incorrectly calculated the adjustment for three out of four Plaintiffs. (Clark *Butler* 95:13–23; 183:19–187:11; 198:11–199:1; 202:19–204:1.) Dr. Clark miscalculated the years of exposure for Ms. Butler, Mr. Hines and Mr. Koterba—meaning Mr. Walick is the only plaintiff whose years of exposure in Dr. Clark's analysis are correct.[2] This failure alone renders Dr. Clark's already flawed opinion for these three Plaintiffs additionally unreliable because their period of exposure is not correct.

Third, Dr. Clark relied on projections and assumptions that do not apply to Plaintiffs and overstate their exposure. For example, Mr. Koterba testified during his deposition that he rode his bike along Coldwater Creek from ages 14 to 18—*i.e.*, for 4 years. (Clark *Butler* 203:18–204:1.) Yet Dr. Clark assumed Mr. Koterba rode his bike along Coldwater Creek from ages 7 to 58—*an overestimation of 47 years*. (*Id*.) Dr. Clark admitted that, based on Mr. Koterba's testimony, his actual bike riding was less than Dr. Clark assumed, but he made no adjustment to his opinions.

[2] *See*, Clark Exposure Analysis for Pamela Butler, March 31, 2019, PDF pgs. 68-70, 80-88,157-165, 234-242; Clark Exposure Analysis for Anthony Hines, March 31, 2019, PDF pgs. 122-131; 194-203; 266-275; Clark Exposure Analysis for Kenneth Koterba, March 31, 2019 PDF pg. 88-90;160-162, 232-234, 67-69, 139-141; 211-213. On September 4, 2019, Clark issued a supplemental report for Plaintiff Emery Walick because the narrative in parts of Walick's original report mistakenly identified Walick as Anthony Hines. Clark's Supplemental Report for Emery Walick corrected this mis-identification but did not change any of the calculations or doses. Since the calculations and doses are the focus in this Motion, Mallinckrodt refers the Court to Clark's March 31, 2019 Report for Emery Walick, instead of the September 4, 2019 Supplement.

(Clark *Butler* 203:23–204:2.) Dr. Clark's failure to incorporate the Plaintiffs' actual information led to similar exaggerated doses for all Plaintiffs. (Clark *Butler* 95:13–96:21; 146:1–147:20; 182:4–187:11; 191:12–195:5; 203:18–204:17; 221:24–223:11.)

Additionally, the Draft ATSDR Report on which Dr. Clark's methodology is exclusively based used the same emission factor (i.e., how much dust is moved into the air) for every exposure activity it analyzed: an emission factor equal to the dust one is exposed to while riding the second of two all-terrain vehicles ("ATVs") on trails in Colorado. Because of its risk-protection purposes, the ATSDR deliberately applied this elevated emission factor to all recreational activities to ensure a conservative exposure assessment. By using this emission factor for his analysis, instead of emission factors for the activities Plaintiffs actually testified doing, Dr. Clark generated overstated doses. (RAC March 17, 2020 Report, p. 14-3, attached as **Exhibit G**.) Surprisingly, Dr. Clark did not know this until his deposition:

- Dr. Clark did not know what the emission factor was that the ATSDR Report used for the recreational activities on which he based his doses. (Clark *Butler* 143:5–9.)
- Dr. Clark did not know the ATSDR Report applied the ATV emission factor to all of its recreational activities—including simply walking or playing by the Creek. (Clark *Butler* 145:4–16.)
- Dr. Clark admitted he was unaware of any of the Plaintiffs ever riding an ATV around Coldwater Creek. (Clark *Butler* 143:20–144:5.)

Thus, Dr. Clark unwittingly based his emission factor on an activity *none* of the Plaintiffs ever engaged in—and incorporated this error into all of his doses.

Finally, Dr. Clark unreliably applied the ATSDR methodology to Plaintiffs by doubling up activities the ATSDR segregated, thus multiplying the Plaintiffs' exposures and doses in an impossible manner. The ATSDR specifically states that its recreational and residential scenarios "are not intended to be added" together because "each represents a high-end estimate for that particular scenario." (Final ATSDR Report, p. 21.) Yet Clark did exactly that. This error led Dr.

Clark to assume the Plaintiffs spent more time engaged in radiation-exposing daylight hour activities than the total amount of daylight hours in a day. (RAC March 17, 2020 Report, p. 14-8.)

As the record shows, Dr. Clark completely failed to perform a dose reconstruction for these Plaintiffs, let alone a reliable one. He simply adopted the ATSDR's hypothetical approach (against their instructions) and applied it incorrectly to the wrong number of years Plaintiffs lived in the area. (Hu *Butler* 198:11–199:1, attached as **Exhibit H**.) Moreover, he admitted his analysis does not reflect the factual information in his possession for these Plaintiffs, which consequently overstates their exposure. (*See, e.g.*, Clark *Butler* 192:13–193:5; 203:18–204:1.) Because Dr. Clark did not use Plaintiff-specific information to calculate his doses, his doses cannot match their actual exposures, are the product of an unreliable method, and are not related to the facts of the case. Fed. R. Evid. 702; *Lauzon v.*, 270 F.3d at 687. Dr. Clark's failure to incorporate the Plaintiffs' information warrants exclusion of his opinions. *See Concord Boat Corp.*, 207 F.3d at 1057 (when an opinion is based on faulty or insufficient data, or otherwise ignores relevant data, it is proper for a district court to exclude such testimony).

2. Dr. Clark's Calculations Carry an 83% Error Rate.

Dr. Clark's analysis should also be excluded because it is replete with mathematical and analytical errors—at an average error rate of 83%. (RAC March 17, 2020 Report, p. 14-9.) *Daubert* requires this Court to consider the known or potential rate of error of the technique or theory when applied. *Daubert,* 509 U.S. at 593–94; Fed. R. Evid. 702, advisory committee's notes. Here, the high error rate renders Clark's opinions fundamentally unreliable.

As Dr. Clark's written report shows, his errors include (1) multiplying by the incorrect exposure duration and then including it multiple times; (2) multiplying organ doses by tissue weighting factors; (3) improperly adding organ doses and effective doses; (4) mixing up soil and sediment exposure times; (5) mixing up intake calculations and age groups; and (6) mixing up

dose coefficients. (RAC March 17, 2020 Report, p. 14-9.) His other errors include basic, transformative mistakes. For example, Dr. Clark used *Ms. Butler's* residential history to calculate *Mr. Hines's* dose. (Clark *Butler* 201:21–202:7.) This error is fatal to Dr. Clark's opinions for Mr. Hines in this case—Mr. Hines' alleged dose is based on someone else's data. (*Id.*)

These errors are unsurprising because Dr. Clark admitted he did not conduct any quality control checks of his work, nor did he engage in any type of peer-review process. (Clark *Butler* 96:22—98:9; Clark *Czapla* 240:7–10.) He also did not validate his dose reconstruction in any way. (Clark *Butler* 141:16–19.) *Daubert* requires that this Court consider whether the expert's method has faced peer review or publication, the existence and maintenance of standards and controls, and whether the technique or theory has been generally accepted in the scientific community. *Daubert*, 509 U.S. at 593–94; Fed. R. Evid. 702, advisory committee's notes. Dr. Clark fails all three.

3. Dr. Clark's Opinions Cannot Be Reproduced, Traced, or Tested.

Dr. Clark also failed to provide sufficient information in his report to allow anyone to trace and replicate his calculations and conclusions. "A key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested." *Daubert*, 509 U.S. at 593. Dr. Clark testified he used a program called ProUCL to come up with his doses. (Clark *Butler* 77:1–6.) Yet he failed to provide these calculations, making them incapable of testing:

> Q: But sitting here today, we have no idea to know what data you used because you didn't produce that; correct?
>
> A: Correct.
>
> Q: Okay. So we just have to take you at your word that 69.9 is correct. Or 62.9 is correct?
>
> A: 62.9, yes.

(Clark *Butler* 85:16–23.)

After the deposition, Mallinckrodt specifically requested the native information and data underlying Dr. Clark's calculations and opinions. While Plaintiffs provided some of the information, the files Dr. Clark provided did not include the native files, precluding anyone from tracing, replicating, or verifying Dr. Clark's calculations. Additionally, the numbers in the files Dr. Clark did provide did not match the original numbers he allegedly relied upon. Dr. Clark's failure to provide the calculations and data he used—so that someone else could replicate, test, or verify his results—is in itself fatal under *Daubert*, *See* 509 U.S. at 593.

C. Dr. Clark Invented a Radiation World That Does Not Exist.

1. Universally Accepted Scientific Standards Contradict Dr. Clark's Manufactured "Natural Background" Number.

One element of Plaintiffs' burden of proof in this case is an obligation to show they were exposed to radiation in an amount above natural background radiation. *In re TMI Litig.*, 193 F.3d 613, 659 (3d Cir. 1999), *amend.* 199 F.3d 158 (3d Cir. 2000.) Realizing this Dr. Clark invented a low "background" number as a hurdle he could overcome. Dr. Clark's testimony will not help "determine a fact in issue," Fed. R. Evid. 702, because the exposure dose he reached for each Plaintiff falls below the scientifically accepted natural background levels of radiation. Dr. Clark's attempt to compensate for his exposure doses by lowering the universally accepted natural background levels to pure fiction underscores his unreliable method and renders his conclusions irrelevant to any scientific endeavor and this case.

Natural background is an important metric in radiation dosimetry because it is a threshold level of radiation to which everyone is exposed. It is also a key marker because there are no harmful effects of radiation exposure below background levels—a statement Dr. Clark does not and cannot refute. (Clark *Butler* 155:20–156:11; Clark *Czapla* 23:4–19.) Natural background levels are well understood in the scientific radiation community and not disputed. It is universally accepted that

the natural background level of radiation in the United States is roughly 360 millirem per year. (Clark *Butler* 175:19–24.) Plaintiffs' experts, including Dr. Clark, admit that the ATSDR Report, the Environmental Protection Agency, and "multiple other agencies" identify this as the correct background number. (Clark *Butler* 151:25–153:21; 175:19–24; Hu *Butler* 96:1–97:19; Hu *Czapla* 9/1/20, 133:2–15, see attached as **Exhibit I**.) Price-Anderson Act caselaw also accepts that number. *See In re TMI Litig.*, 193 F.3d at 659 (the total average annual background dose, is 3.6 mSv or 360 mrem); *McMunn v. Babcock & Wilcox Power Generation Grp.*, 869 F.3d 246, 352 (3d Cir. 2017) (same).

But Dr. Clark did not use the scientifically accepted natural background in his methodology (even though his ATSDR source methodology did) and instead created his own. (Clark *Butler* 124:4–125:8; 216:6–11; Clark *Czapla* 24:19–25:18.) Dr. Clark calculated his own natural background numbers by using only select locations and only certain radionuclides as if those were the only locations and radionuclides causing exposure. This is nonsensical: by definition, background radiation is everywhere, exposing all of us all the time.

Dr. Clark's "background" numbers range from 0.9 to 55.0 millirem for the Plaintiffs' *entire exposure period*, in contrast to the widely accepted background level of 360 millirem *per year*.[3] For obvious reasons, Dr. Clark preferred to use a fictional low background number to make his insignificant doses appear significant. Dr. Clark admitted he has never seen *anyone* calculate radiation background in the manner he does. (Clark *Butler* 217:22–218:14.) Plaintiffs' own causation expert, Dr. Hu, admitted the same. (Hu *Butler* Dep., 97:12–19; 108:19–110:16.)

[3] *See* Clark Exposure Analysis for Pamela Butler, March 31, 2019, PDF p. 141; Clark Exposure Analysis for Anthony Hines, March 31, 2019, PDF p. 156; Clark Exposure Analysis for Kenneth Koterba, PDF p. 135; Clark Exposure Analysis for Walick, March 31, 2019, PDF p. 135.

When, as here, the relevant literature does not support the expert's methodology, the expert testimony should be excluded. *See, e.g.*, *Good*, 222 F. Supp. 2d at 1245 (excluding expert in Price-Anderson Act case because literature did not support methodology for estimating alpha radiation exposure); *Kumho Tire*, 526 U.S. at 157 (excluding expert because of lack of evidence methodology was used by other experts in industry and no supporting literature). By rejecting actual, known, universally established and accepted background radiation levels and inventing his own made-for-litigation background levels, Dr. Clark rendered his opinions unreliable under *Daubert*. *See Lauzon*, 270 F.3d at 687; *Castellow v. Chevron USA*, 97 F. Supp. 2d 780, 786 (S.D. Tex. 2000) ("work[ing] backward" from conclusion to find scientific support is a practice that "cannot withstand *Daubert* scrutiny and is not due any credence in a court of law").

2. Dr. Clark's "Reasonable Maximum Exposure" Dose Overstates the Exposure without any Basis to Reach this Litigation-Desired Result.

With his litigation-designed background numbers creating a falsely low threshold level, Dr. Clark then took an unsound approach to dose calculation by generating an exposure dose for each Plaintiff based on their "reasonable maximum exposure" (RME), which dramatically multiplied his already flawed doses discussed above. Dr. Clark's RME is "the highest exposure that is reasonably expected to occur at a site." (Clark *Butler* 82:1–84:3.) He described his invention as calculating the "upper confidence limit of the average" and "well above the average." (Clark *Butler* 83:19–84:3; *see also* Hu *Czapla* 8/31/20, 47:6–25, attached as **Exhibit J**.) Dr. Clark's intentional use of this purely fictional dose overstates the exposure and is another ground for excluding Dr. Clark's opinions. *See Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814 (W.D. Tex. 2005).

In *Cano*, plaintiffs also alleged they developed cancer from defendants' activities—there, uranium mining and milling. The plaintiffs' expert calculated his radiation dose by taking the

average organ dose from ranges estimated by another expert, rather than basing it on plaintiff-specific data. *Id.* at 858. The court found the use of an average number range to be "questionable": "The farther you get from the low number, which you know must be true in the sense that it must be at least that, the more speculative the opinion becomes." *Id*. Dr. Clark's opinion is far more outrageous: he ignored the Plaintiffs' specific exposure information and instead used ATSDR's conservative assumptions for each of the four Plaintiffs, which led to inflated exposures. (Clark *Butler* 183:5–18.) He then calculated his dose using the 95% upper confidence limit of the average of these exposures, which further inflated the dose with no basis, far beyond the expert in *Cano*. (*E.g.*, Clark *Czapla* 82:2–84:3 (used 95% upper confidence limit so as not to "underestimate" potential exposure).)

As a result, Dr. Clark admits the doses he calculates are "well above" the average by their very nature, and they should therefore be excluded.

3. Dr. Clark's "Maximum" Doses Should Be Excluded Because They Represent an Impossible Scenario.

In addition to his RME doses, Dr. Clark calculated a "maximum" dose for each Plaintiff calculating the highest dose possible. (*See, e.g.*, Clark Pamela Butler report at p. 293, attached as **Exhibit K**.) Dr. Clark's "maximum" dose was not a subject of his deposition because at the time he was deposed, on September 18, 2019, Plaintiffs were not relying on his maximum dose for causation. Neither Dr. Clark nor Plaintiffs' medical expert, Howard Hu, M.D., relied on the maximum doses in their April 2019 reports; nor did either say it was an appropriate dose to adjudge causation in this case. (*See* Clark's Reports; *see also* Howard Hu. M.D., April 1, 2019 Reports; *cf.* Howard Hu, M.D., September 30, 2019 Addenda.) However, shortly after Clark's deposition, on September 30, 2019, Dr. Hu produced Addenda to his reports and for the first time relied on Clark's maximum dose for causation. (*Id.*)

Dr. Clark's invented "maximum" doses are based on the highest recorded measurements of Thorium-230, Radium-226 and Uranium-238 that Dr. Clark could find in the thousands of data points sampled in the area.[4] And the highest recorded measurements Dr. Clark used did not come from one single sample, but *three different* samples taken in *different* geographic locations. (RAC March 17, 2020 Report, p. 14-10.) The selection mechanism blatantly inflated the data.

Dr. Clark then assumed that each Plaintiff was exposed, for their entire exposure period, to those highest ever measurements in each of these geographic locations—simultaneously.[5] In other words, Dr. Clark assumed a physically impossible premise, requiring each Plaintiff to be in three different locations simultaneously for their entire exposure time. Further, these three measurements are from the SLAPS and Latty Avenue fence lines (*see* RAC Figure 14-2), but *none* of the Plaintiffs testified that they were ever near the fence lines for SLAPS or Latty Avenue, much less simultaneously at multiple locations on the fence lines for their entire exaggerated exposure periods, as Dr. Clark assumed for his maximum doses.

The Court should exclude these maximum doses because they are a litigation-inspired fiction invented to inflate Plaintiffs' doses. Because it was physically impossible for Plaintiffs to have received these doses—a fact even Dr. Hu acknowledges—the conclusions cannot possibly result from a reliable method under *Daubert.* (Hu *Butler* 214:3–216:2).

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[4] *See* Clark Exposure Analysis for Pamela Butler, March 31, 2019, PDF p. 293; Clark Exposure Analysis for Anthony Hines, March 31, 2019, PDF p. 298, attached as **Exhibit L**; Clark Exposure Analysis for Kenneth Koterba, PDF p. 277, attached as **Exhibit M**; Clark Exposure Analysis for Walick, March 31, 2019, PDF p. 277, attached as **Exhibit N**.

[5] *See* Clark Exposure Analysis for Pamela Butler, March 31, 2019, Appendix C3, PDF pp. 217–293; Clark Exposure Analysis for Anthony Hines, March 31, 2019, Appendix C3, PDF pp. 277–298; Clark Exposure Analysis for Kenneth Koterba, Appendix C3, PDF pp. 206–277; Clark Exposure Analysis for Walick, March 31, 2019, Appendix C3, PDF pp. 206–277.

D. Dr. Clark Is Not Qualified to Opine on Radiation Exposure or Cancer Risk.

1. Dr. Clark Is Not Qualified to Opine on Radiation Dose Exposure.

There is an obvious reason for the multitude of egregious errors Dr. Clark made. Radiation is a "highly technical area." *McMunn*, 869 F.3d at 267. Radiation dose reconstruction in particular is a highly specialized field requiring training in several disciplines, most notably radiation science. Dr. Clark, however, has no educational background or professional training in radiation science. Dr. Clark claims he is "self-taught" in the field—starting with this series of cases. (Clark *McClurg* 10/4/17, 81:18–21.) His lack of dosimetry training and knowledge shows throughout his report in its many errors and flawed methodology, discussed in detail above, resulting in doses that: (1) do not consider Plaintiff-specific information in Dr. Clark's possession; (2) cannot be reproduced, traced and tested; and (3) contain an 83% error rate in their calculations.

Under Rule 702, an expert must be qualified by "knowledge, skill, experience, training, or education" to offer opinion testimony. "The trial court ha[s] to decide whether this particular expert ha[s] sufficient specialized knowledge to assist the jurors in deciding the particular issues in this case." *Omega Flex, Inc.*, 783 F.3d at 723 (alterations original). The Eighth Circuit will affirm the exclusion or reverse the admission of testimony where an expert strays beyond their expertise. *Id.* at 724. In weighing an expert's qualifications, the court should consider "whether the expertise was developed for litigation or naturally flowed from the expert's research." *Presley v. Lakewood Eng. & Manuf. Co.*, 553 F.3d 638, 643 (8th Cir. 2009).

Moreover, expert qualifications in one area will not qualify the expert to testify in another area. *See Marmo*, 457 F.3d at 758; *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001). In *Marmo*, for example, the Eighth Circuit held that an expert was qualified in the field of toxicology but not qualified to testify to medical causation for the specific plaintiff. 457 F.3d at 758. The expert's testimony was subject to exclusion because the

expert did not examine the plaintiff, did "not exclude confounding factors," and "admitted that the causation standard she employed was not subject to expression in terms of a potential rate of error and was a much lower standard than medical causation." *Id.*

Here, Dr. Clark is seeking to testify in the field of radiation dosimetry and yet has no experience in this field. Dr. Clark has never published on radiation dosimetry. (Clark *Butler* 13:24–14:2.) He is not a health physicist, radiation biologist, radiation dosimetrist, or mathematical modeler. (Clark *Butler* 16:4–6; Clark CV, attached as **Exhibit O**.) He is not a member of any professional societies specific to radiation. (Clark *Butler* 15:8–19:23.) He has never served on a national or international scientific committee related to radiation or any other relevant discipline. (*Id*.) His publications show no articles at all related to radiation exposure or radionuclides in the environment. (Clark *Butler* 13:24–14:2, Clark CV.) He also admitted he has taken no coursework in the relevant topics of nuclear engineering, nuclear physics, or radiation dosimetry. (Clark *McClurg* 10/4/17, 80:4–81:21.) Before the *McClurg* litigation, Dr. Clark had never calculated a radiation dose. (Clark *Butler* 14:17–15:7; *see also* Clark *Czapla* 160:2–13.) He simply claimed to be "self-taught" on the models he has tried to use in this litigation. (Clark *McClurg* 10/4/17, 81:18–21.)

Dr. Clark's lack of qualification to opine on radiation is evidenced by his lack of understanding of simple radiation measurements and terms. For example, Dr. Clark is unable to define or explain basic terms used in the field such as effective dose or even radiation exposure. (Clark *Butler* 108:2–112:10.) He does not know the difference between very basic radiation measurement units such as the Gray and Sievert. (Clark *McClurg* 10/4/17, 120:2–13.) Likewise, when asked to define the "probability of causation"—a measure of how likely it is that a cancer was "at least as likely as not" caused by exposure to ionizing radiation—Dr. Clark stated, "I'm

blanking on that right now." (Clark *Butler* 112:8–16.) Clark also confused the terms "activity" and "dose," which a qualified expert trained in radiation dosimetry would never do because it is analogous to measuring the temperature of a room in centimeters. (Clark *McClurg* 10/4/17, 181:20–182:9; RAC March 17, 2020 Report, p. 14-3.)

In other words, radiation science and the methodology for determining radiation doses is well beyond Dr. Clark's knowledge, skill, experience, education, or training as a toxicologist. Accordingly, Dr. Clark's testimony should be excluded based on his non-existent qualifications, experience, and training in the field of radiation.

2. By His Own Admission, Dr. Clark Is Not Qualified to Opine on Cancer Risk.

Dr. Clark is also not qualified to opine, as he does, that the four Plaintiffs suffer from increased risks of cancer due to their alleged radiation exposures. He is not a medical doctor or health physicist. (Clark *Butler* 20:16–18; 16:4–9.) He admitted he did not even attempt to research any published studies or epidemiological literature to support his opinion that Plaintiffs have an increased risk of cancer or other illness. (Clark *Butler* 215:24–216:5; *see also* Clark *Czapla* 127:15–18 (conceding he does not know the background risk of cancer in men).)

In radiation litigation arising out of the nuclear reactor incident at Three Mile Island, the Third Circuit affirmed the exclusion of testimony about the health effects of radiation by a non-medical expert: the expert was "neither a medical doctor nor a health physicist. So far as the record is concerned, his only knowledge of the health effects of radiation was obtained from literature he reviewed in connection with his retention as an expert in this litigation. He plainly does not meet Rule 702's 'Qualifications' requirement and cannot, therefore, offer an expert opinion as to radiation-induced medical conditions." *In re TMI Litig.*, 193 F.3d at 680.

Dr. Clark is *less* qualified than the expert in *In re TMI* to offer his opinions on the Plaintiffs' increased cancer risks since he has not even reviewed the relevant epidemiological literature. S*ee also Kumho Tire Co.*, 526 U.S. at 157 (expert without supporting literature properly excluded). Simply put, Dr. Clark's opinion that Plaintiffs are at an increased risk of cancer from their alleged exposure is unfounded, and Dr. Clark is not qualified to give such an opinion. Thus, Dr. Clark should be excluded from offering opinions related to Plaintiffs' increased risks of cancer.

V. CONCLUSION

For these reasons, Defendants request that this Court enter an Order excluding Dr. Clark's testimony because it does not meet the requirements for admissibility under Federal Rule of Evidence 702 and *Daubert*.

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Respectfully submitted,

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I hereby certify that on the 18th day of August 2021, I served the above to the following counsel of record via the Court's electronic filing system.

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